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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No.39

Application Number: 09082112
Filing Date: 20 May 1998
Appellant(s): Mendoza et al.

Ian C. McLeod
For Appellant

# EXAMINER'S ANSWER

This is in response to appellant's brief which is the only brief considered on appeal filed 16 July 2002 (hereinafter, the Brief).

***(1) Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

***(2) Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the

brief.

*(3) Status of Claims*

The statement of the status of the claims contained in the brief is correct.

*(4) Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

*(5) Summary of Invention*

The summary of invention contained in the brief is essentially correct. However, it is noted that the language pertaining to the exemplary vaccine of the specification and its preparation as noted in Example 1 differs from the language used to describe the vaccine as claimed. In particular, Example 1 notes the relevant steps pertaining to the preparation of the vaccine whereas the claims attempt to describe "essentially" that material prepared which is the vaccine.

*(6) Issues*

The Appellant's statement of the issues in the brief is correct.

*(7) Grouping of Claims*

Appellant's brief includes a statement that claims 16-25 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

*(8) Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

*(9) Prior Art of Record*

The prior art relied upon by the examiner in the rejection of the claims under appeal is as follows:

Mendoza et al, J. Mycol. Med, 1996, 6:151-164.

Mendoza et al, Mycopathologica, 1992(a), 119:89-93, (IDS: Ref. AI).

Mendoza et al, J. Clin. Microbiology, Nov. 1992(b), p. 2980-83.

Sigma Catalog, p.1874, 1992.

Amicon Catalog, p. 35, 1993.

Mendoza et al., Abstract, Third NIAID Workshop in Medical Mycology Series, September 7-9, 1995.

***(10) Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claim 19 and 24 are rejected under 35 USC 112, second paragraph. This rejection is set forth in the prior Office Action of 8-13-01, Paper No. 32. The claims are rejected as being indefinite for the recitation of "removing the disrupted cells to provide the mixed intracellular proteins".

As set forth therein, such recitation is indefinite to the skilled artisan as to what is being removed or what steps are being performed. Appellant's were suggested to recite a step which may be discerned by the artisan such as removing insoluble material by centrifugation.

For example the specification in Example 1 sets forth steps for the preparation of the vaccine yet claims the vaccine in different method terms. The artisan fails to recognize separable intracellular and extracellular material. Appellants appear to be referring to the removal of insoluble cellular material via centrifugation and removal of the supernatant with discarding of the pellet. Yet the artisan does not readily recognize how removal of disrupted cells may be achieved

and therefore the recited step is indefinite as to what step is being performed and its subsequent effect on the vaccine prepared by the recited method. Clarification is required.

Claims 16-25 are rejected under 35 U.S.C. 103(a). This rejection is set forth in the prior Office Action of 8-13-01, Paper No. 32. As set forth therein, the claims are rejected as being unpatentable over Mendoza et al, J. Mycol. Med, 1996, 6:151-164, Mendoza et al, Mycopathologica, 1992(a), 119:89-93, (IDS: Ref. AI), Mendoza et al, J. Clin. Microbiology, Nov. 1992(b), p. 2980-83, Sigma Catalog, p.1874, 1992, Amicon Catalog, p. 35, 1993 and Mendoza et al., Abstract, Third NIAID Workshop in Medical Mycology Series, September 7-9, 1995.

As further stated therein, the examiner notes that Appellant's fail to acknowledge that the suggestion of the combination and the effect of curing chronically infected horses are provided in the prior art. Specifically, the prominent cytoplasmic (intracellular) antigens were added as described in Mendoza et al., J. Clin. Microbiol., 30:2980-2983, 1992(b) to the SCAV vaccine (mixed extracellular preparation). Mendoza et al., Abstract 1995, teaches that the addition of the 28-32 kD immunodominant (intracellular) peptides to the culture filtrate proteins leads to the cure of 8 chronically infected horses. As discussed in the Mendoza et al., 1992(b) reference, Mendoza thus teaches that the addition of intracellular cytoplasmic antigens provides for the improved vaccine which cures chronically infected horses. In detail and as set forth in the specification at page 6, line 15, the improved vaccine (was) prepared by adding cytoplasmic antigens to the earlier *P. insidiosum*-vaccine (Mendoza et al., Mycopathologica 119:89-95 (1992(a))). Mendoza et al, 1992(a) disclose two prior art vaccines, a cell-mass vaccine (CMV) and a soluble concentrated antigen vaccine (SACV). Mendoza et al., Abstract 1995, teaches that the addition of the 28-32 kD (intracellular) immunodominant peptides to culture filtrate proteins leads to the cure of 8 chronically infected horses. As discussed, the Mendoza et al., 1992(b), reference thus suggests

and teaches the combination of mixed intracellular and mixed extracellular antigens as claimed and thus provides the motivation for the improved vaccine in addition to its' expected benefits, curing chronically infected horses. The methodology disclosed for the preparation of the two vaccines and the isolation of the three added immunodominant peptides are referenced at p. 2981, column 1 as disclosed in Mendoza et al., J. Clin. Microbiol., 30:2980-83, 1992. Mendoza clearly evidences that the three immunodominant proteins which are added to the improved vaccine are present in the CMV preparation, represent immunodominant peptides and further suggests that such peptides may be useful for diagnostic and immunotherapeutic effects in horses, see in particular abstract and 2981, column 1, including for the treatment of chronically infected horses, see in particular Mendoza et al., 1995 and 1996.

The fact that the CMV vaccine alone was not able to cure chronically infected horses is not a teaching that the CMV preparation contained components which inhibited the curative properties of the immunodominant proteins as the comparative data provided is insufficient to arrive at such conclusion. In contrast, the prior art does not teach that the immunodominant proteins are the critical element. The prior art teaches that a combination of the SCAV (extracellular) preparation with the addition of the immunodominant proteins (contained in the CMV preparation) was the critical combination. Thus, the suggestion of the prior art is that the combination of mixed intracellular and extracellular proteins provide the enhanced curative properties to chronically infected horses. In addition, upon such teaching, the combination of the CMV (containing the immunodominant proteins) and the SCAV (mixed extracellular) proteins would have been prima facie obvious to the artisan, particularly in that the combination of the two preparations would provide the required constituents yet would be easier in preparation than providing only the isolated immunodominant proteins because there would be no need for the additional preparative steps including isolation of the 28-32 kD antigens via gel electrophoresis, recovery from the gel and addition to the SCAV vaccine. Thus, in contrast to Appellant's

suggestion, the prior art suggests the mixture of intracellular and extracellular proteins and the artisan would recognize that the easiest way of performing such combination would be to combine the intracellular (CMV) and extracellular (SCAV) preparations of the prior art which have been shown to contain the minimal essential elements required for curing chronically infected horses. It is noted that as the claims recite comprising language, the elements of the claimed invention i.e., mixed intracellular and mixed extracellular proteins are provided and are within the scope of the claim regardless of whether all of the intracellular antigens or merely the immunodominant intracellular antigens are provided. *All* of the intracellular proteins are not required by the claims. The steps provided in the claims are those for the preparation of the CMV and SCAV vaccines. It is further noted that there is no comparative data which demonstrates different or unexpected effects which are attributed to a preparation containing all the intracellular proteins in comparison to one containing only the immunodominant peptides.

It is further noted that Appellant's claims are not directed to a preparation "consisting of all the extractable intracellular proteins with the extracellular proteins." In addition, it is noted that the Sigma reference is directed to the equivalent step of removing low molecular weight constituents via a PM-10 membrane as disclosed for example in Mendoza et al., J. Clin. Microbiol., Nov. 1992, p. 2980-83 as set forth in p. 8-9 of the office action mailed 11-7-00 and the limitation as recited in the method of claims 16-25 of "dialyzing the resuspended proteins in sterile water to remove material less than 10,000 MW". The method/process limitations of filtration via ultracentrifugation, or a stir cell through a PM-10 membrane ,each removes small peptides and impurities as set forth previously and in particular is evidenced by Table 19 of the provided Amicon catalog p. 35. This step is an obvious equivalent which does not appear to result in a patentably distinguishable product from that of dialysis to remove small peptides and impurities because the molecular weight cut offs for the PM-10 membrane and a dialysis membrane are similar as evidenced by Sigma, Amicon and Mendoza et al., 1992(b). Sigma

teaches dialysis tubing with a molecular weight cutoff of approximately 12,400 MW and PM-10 membrane of MW cut-off of 10,000 MW. The examiner provides herein the MW of Thimerosal as evidenced by Sigma, p. 952 of 404.8 MW and thus it is clear that Thimerosal would be removed by either dialysis or ultracentrifugation through a PM-10 membrane. Thus, the Sigma reference is relevant to the claimed method steps.

It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Without arguing the evolutionary descent of horses and humans, suffice it to say that the artisan at least recognizes horses and humans as common mammals which exhibit strikingly similar immune response mechanisms as previously set forth in Paper No. 23, 1107-00, pp. 10-11 including T cells, B cells, antibodies, cytokines etc.. Thus, there is no apparent reason why the artisan would a priori determine that an efficacious vaccine in horses would necessarily fail to be beneficial to humans. Further evidence suggests that the artisan would expect that the combined prior art vaccine would possess similar protective responses in horses and humans. In particular Mendoza et al., 1996 clearly indicate the similarity in human and animal Pythiosis infections, the need for treatment in humans as noted above that the same immunodominant antigens were recognized in horse and in human sera and that these immunodominant antigens correspond to the 28-32 kD immunodominant antigens contained in the CMV intracellular preparation which have been shown to provide the enhanced curative properties in chronically infected horses when combined with the SCAV extracellular vaccine of the prior art. Thus, based on Mendoza et al., 1996 the artisan would have motivation to provide the combined vaccine to humans and would further expect beneficial results based on the evidence that the critical immunodominant epitopes

required for protection in horses and humans are the same. Thus based on the cumulative reference teachings the claimed invention is rendered prima facie obvious to the skilled artisan. There are no method steps as claimed which are not provided by the prior art and the motivation and expectation of success for the combination are provided by the reference teachings.

Consistent with case law and as set forth in the MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)."

***(11) Response to Argument***

With respect to 35 USC 112, second paragraph, Appellants argue at p. 8 of the brief that the phrase "removing the disrupted cells to provide the mixed intracellular proteins" is believed to clearly inform a person of ordinary skill in the art what is being removed. Appellant's argue that the skilled artisan would know that killed cell debris is insoluble in sterile water and that the most common method for removing the disrupted cells is centrifugation and that after centrifugation, the supernatant fraction would contain the mixed intracellular proteins which would be soluble. Example 1 notes the steps in preparation including disrupting the killed cells in sterile water by sonication and then removal of the killed cells by centrifugation.

In response, the Examiner notes that as previously argued in the record, disruption of cells results in the lysis of the cell wall, breakage of cellular proteins and the release of both soluble and insoluble components from the cells. These components comprise soluble and insoluble materials. It is not agreed that all of the soluble material is intracellular and all of the insoluble material is extracellular. Such is known to the artisan and therefore the artisan would not conclude that the soluble material was of only mixed intracellular proteins and that removal of the insoluble portion via centrifugation or any other method, would necessarily result in a solution of "mixed intracellular proteins" as claimed. The language of the claims describes "separating the killed

cells from the culture medium to produce a first supernatant to provide the mixed extracellular proteins of (a) (2) and then disrupting the killed cells in sterile water and removing the disrupted cells from the sterile water containing the mixed intracellular proteins to provide the mixed intracellular proteins of (a) (1) in a second supernatant...." The step requires "disrupting the cells in sterile water and removing the disrupted cells," to provide "mixed intracellular proteins" yet the artisan only recognizes for example removing insoluble material. Removing disrupted cells could refer to removal of the protein matter but this would not result in mixed intracellular proteins, but of near sterile water. Removing disrupted cells could refer to removing soluble material or insoluble material but this would also not result in mixed intracellular proteins , but either a solution of mixed soluble intracellular proteins and mixed soluble extracellular proteins or a pellet of mixed insoluble intracellular proteins and mixed insoluble extracellular proteins. Thus, the artisan cannot clearly discern those steps required to be performed and the necessary results of those steps because the language is not readily discerned by the artisan. Thus, the claims reference to such steps and required results remain indefinite as to the vaccine, its' preparation and its' constituents.

With respect to 35 USC 103, Appellants argue at p. 9-19 that in the present case the prior art shows no suggestion or motivation to combine the prior art references to produce and use a vaccine such as that claimed for treating mammals or humans with any expectation of success. In particular at p. 10 Appellant summarizes their vaccine. At p. 11, Appellants argue that the prior art does not recognize the possibility of treating humans with the claimed vaccine. At p. 11-13 Appellants argue Mendoza 1992a, Mendoza 1992b and Mendoza 1995, as to select teachings and conclude that their teachings together would not arrive at the vaccine claimed for the treatment of chronically infected horses or for the treatment of humans. At. p.14 Appellants point to undesirable attributes of the CMV vaccine namely a short shelf-life, limited efficacy and a

prominent inflammatory response at the inoculation site. Appellants point to particular preparations which contain material less than 10, 000 MW as teaching away from Appellant's improved vaccine and conclude that the art provides no motivation for treatment in humans. Appellants at p. 15 -17 argue that the teachings of Sigma and Amicon do not render their preferred preparations obvious as a stir cell does not remove material less than 10,000 MW as does dialysis. At p. 18, Appellants argue that the only way to arrive at the claimed invention is to use the specification as prior art.

In response, it is noted that Appellants refer to characteristics of the vaccine which are not claimed. In particular, the claims do not recite the limitations of all the soluble intracellular proteins and the extracellular proteins in a mixture. Appellants further appear to point out unexpected characteristics of their "improved vaccine", yet it is noted that the apparent "improved" characteristics are not to the vaccine as claimed but to a particular preparation whose constituents are not adequately described by the claims. As set forth in the record the vaccine of the claims does not appear to be an accurate description of the exemplary vaccine or the essential elements it contains as it is prepared in Example 1. Further, the language chosen to describe the vaccine as claimed does not fairly represent an unobvious preparation in comparison to that of the prior art, regardless of the use of the new language used to describe the preparation. The prior art references of Mendoza 1992a, Mendoza 1992b and Mendoza 1995 each teach vaccines with mixed intracellular proteins and mixed extracellular proteins as prepared.

Moreover, as to the preferred exemplary vaccine (Example 1) to which Appellants appear to be referring, the prior art of record discloses it's preparation and the successful treatment of chronically infected horses, the similarity of immunodominant epitiopes and immune responses in humans as well as a need for vaccination in humans to treat pythiosis infections. Specifically, the prominent cytoplasmic (intracellular) antigens were added as described in Mendoza et al., J. Clin.

Microbiol., 30:2980-2983, 1992(b) to the SCAV vaccine (mixed extracellular preparation). Mendoza et al., Abstract 1995, teaches that the addition of the 28-32 kD immunodominant (intracellular) peptides to the culture filtrate proteins leads to the cure of 8 chronically infected horses. As discussed in the Mendoza et al., 1992(b) reference, Mendoza thus teaches that the addition of intracellular cytoplasmic antigens provides for the improved vaccine which cures chronically infected horses. In detail and as set forth in the specification at page 6, line 15, the improved vaccine (was) prepared by adding cytoplasmic antigens to the earlier *P. insidiosum*-vaccine (Mendoza et al., Mycopathologica 119:89-95 (1992(a))). Mendoza et al, 1992(a) disclose two prior art vaccines, a cell-mass vaccine (CMV) and a soluble concentrated antigen vaccine (SACV). Mendoza et al., Abstract 1995, teaches that the addition of the 28-32 kD (intracellular) immunodominant peptides to culture filtrate proteins leads to the cure of 8 chronically infected horses. As discussed, the Mendoza et al., 1992(b), reference thus suggests and teaches the combination of mixed intracellular and mixed extracellular antigens as claimed and thus provides the motivation for the improved vaccine in addition to its expected benefits, curing chronically infected horses. The methodology disclosed for the preparation of the two vaccines and the isolation of the three added immunodominant peptides are referenced at p. 2981, column 1 as disclosed in Mendoza et al., J. Clin. Microbiol., 30:2980-83, 1992. Mendoza clearly evidences that the three immunodominant proteins which are added to the improved vaccine are present in the CMV preparation, represent immunodominant peptides and further suggests that such peptides may be useful for diagnostic and immunotherapeutic effects in horses, see in particular abstract and 2981, column 1, including for the treatment of chronically infected horses, see in particular Mendoza et al., 1995 and 1996.

The fact that the CMV vaccine alone was not able to cure chronically infected horses is not a teaching that the CMV preparation contained components which inhibited the curative properties of the immunodominant proteins as the comparative data provided is insufficient to

arrive at such conclusion. In contrast, the prior art does not teach that the immunodominant proteins are the critical element. The prior art teaches that a combination of the SCAV (extracellular) preparation with the addition of the immunodominant proteins (contained in the CMV preparation) was the critical combination. Thus, the suggestion of the prior art is that the combination of mixed intracellular and extracellular proteins provide the enhanced curative properties to chronically infected horses. In addition, upon such teaching, the combination of the CMV (containing the immunodominant proteins) and the SCAV (mixed extracellular) proteins would have been prima facie obvious to the artisan, particularly in that the combination of the two preparations would provide the required constituents yet would be easier in preparation than providing only the isolated immunodominant proteins because there would be no need for the additional preparative steps including isolation of the 28-32 kD antigens via gel electrophoresis, recovery from the gel and addition to the SCAV vaccine. Thus, in contrast to Appellant's suggestion, the prior art suggests the mixture of intracellular and extracellular proteins and the artisan would recognize that the easiest way of performing such combination would be to combine the intracellular (CMV) and extracellular (SCAV) preparations of the prior art which have been shown to contain the minimal essential elements required for curing chronically infected horses. It is noted that as the claims recite comprising language, the elements of the claimed invention i.e., mixed intracellular and mixed extracellular proteins are provided and are within the scope of the claim regardless of whether all of the intracellular antigens or merely the immunodominant intracellular antigens are provided. *All* of the intracellular proteins are not required by the claims. The steps provided in the claims are those for the preparation of the CMV and SCAV vaccines. It is further noted that there is no comparative data which demonstrates different or unexpected effects which are attributed to a preparation containing all the intracellular proteins in comparison to one containing only the immunodominant peptides.

It is further noted that Appellant's claims are not directed to a preparation "consisting of all the extractable intracellular proteins with the extracellular proteins." In addition, it is noted that the Sigma reference is directed to the equivalent step of removing low molecular weight constituents via a PM-10 membrane as disclosed for example in Mendoza et al., J. Clin. Microbiol., Nov. 1992, p. 2980-83 as set forth in p. 8-9 of the office action mailed 11-7-00 and the limitation as recited in the method of claims 16-25 of "dialyzing the resuspended proteins in sterile water to remove material less than 10,000 MW". The method/process limitations of filtration via ultracentrifugation or a stir cell through a PM-10 membrane remove small peptides and impurities as set forth previously and in particular is evidenced by Table 19 of the provided Amicon catalog p. 35. Again, a stir cell removes small constituents with a molecular weight less that 10,000 MW. The small constitutens flow through the membrane with the wash fluid. This step is an obvious equivalent which does not appear to result in a patentably distinguishable product from that of dialysis to remove small peptides and impurities because the molecular weight cut offs for the PM-10 membrane and a dialysis membrane are similar as evidenced by Sigma, Amicon and Mendoza et al., 1992(b). Sigma teaches dialysis tubing with a molecular weight cutoff of approximately 12,400 MW and PM-10 membrane of MW cut-off of 10,000 MW. The examiner provides herein the MW of Thimerosal as evidenced by Sigma, p. 952 of 404.8 MW and thus it is clear that Thimerosal would be removed by either dialysis or ultracentrifugation through a PM-10 membrane. Thus, the Sigma reference is relevant to the claimed method step and the removal of constituents of less than 10,000MW.

It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The obviousness rejection is based upon the disclosure in the prior art references and not by the specification. However, it is noted that the specifications exemplary embodiments are largely the same as of the prior art, see in particular Mendoza 1995 and 1996.

Without arguing the evolutionary descent of horses and humans, suffice it to say that the artisan at least recognizes horses and humans as common mammals which exhibit strikingly similar immune response mechanisms as previously set forth in Paper No. 23, 1107-00, pp. 10-11 including T cells, B cells, antibodies, cytokines etc.. Thus, there is no apparent reason why the artisan would a priori determine that an efficacious vaccine in horses would necessarily fail to be beneficial to humans. Further evidence suggests that the artisan would expect that the combined prior art vaccine would possess similar protective responses in horses and humans. In particular Mendoza et al., 1996 clearly indicate the similarity in human and animal Pythiosis infections, the need for treatment in humans as noted above. The same immunodominant antigens were recognized in horse and in human sera and these immunodominant antigens correspond to the 28-32 kD immunodominant antigens contained in the CMV intracellular preparation which have been shown to provide the enhanced curative properties in chronically infected horses when combined with the SCAV extracellular vaccine of the prior art. Thus, based on Mendoza et al., 1995 and 1996 the artisan would have motivation to provide the combined vaccine to humans and would further expect beneficial results based on the evidence that the critical immunodominant epitopes required for protection in horses and humans are the same. Thus based on the cumulative reference teachings the claimed invention is rendered prima facie obvious to the skilled artisan. There are no method steps as claimed which are not provided by the prior art and the motivation and expectation of success for the combination are provided by the reference teachings.

Consistent with case law and as set forth in the MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same

purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)."

Therefore, for reasons set forth above, Appellant's arguments have been fully and carefully considered, but are not sufficient to rebut the prima facie case of indefiniteness and obviousness, and it is believed that the rejections should be sustained.

Respectfully submitted,

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10/21/02

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